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Can electrically-assisted bicycles be recommended for patients with heart disease?

Submission date
16/06/2015

Recruitment status
No longer recruiting

Registration date
08/07/2015

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cardiac rehabilitation is proven to be effective in coronary artery disease patients and is recommended by the European Society of Cardiology. However the long-term benefits are often poor, because patients do not adopt healthy lifestyle behaviours (including regular exercise training). To overcome this problem, alternative rehabilitation methods have been assessed. Especially for the elderly, electrically-assisted cycling could be a valuable alternative to classical cycling. There is little evidence about this approach and the aim of this observational study is to find out more.

Who can participate?
Adult patients diagnosed with coronary artery disease.

What does the study involve?
Participants perform the same route three times in Hasselt, Belgium. The first time they use a classical bicycle, the second and/or third time an electrically-assisted bicycle. During each cycling period, a number of measurements are taken.

What are the possible benefits and risks of participating?
A risk is that participants could experience exercise-related complications during the cycling period. However, participants are supervised by at least one person who can intervene whenever necessary.

Where is the study run from?
Jessa Hospital, Hasselt (Belgium)

When is the study starting and how long is it expected to run for?
November 2014 to April 2015

Who is funding the study?
Heart Center Hasselt (Belgium)

Who is the main contact?
Professor Dominic Hansen

Contact information

Type(s)
Scientific

Contact name
Prof Dominique Hansen

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparing the metabolic load of electrically-assisted cycling with classical cycling in coronary artery disease patients after phase II of cardiac rehabilitation.

Study objectives
The metabolic load of electrically-assisted cycling is significantly different, compared to classical cycling in coronary artery disease patients after phase II of cardiac rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Jessa Hospital Ethics Committee, 07/112014, ref 14.73/reva14.10.

Study design

Single-centre prospective observational trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
ot available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Patients with coronary artery disease, treated with percutaneous coronary intervention or coronary artery bypass grafting.

Interventions
Every patient was requested to perform a cycling route (of 10 km) in Hasselt (Belgium). Patients performed the cycling route 3 times.
The first time, a classical bicycle was used. The second and/or third time electrically assisted bicycles were used (light and heavy assistance).

Intervention Type
Other

Primary outcome measure
VO2, assessed by ergospirometry (Oxycon mobile device) during whole cycling sessions.

VO2 was recorded during all cycling sessions.

Secondary outcome measures
1. VCO2, assessed by ergospirometry (Oxycon mobile device) during whole cycling sessions
2. RER, assessed by ergospirometry (Oxycon mobile device) during whole cycling sessions
3. VE, assessed by ergospirometry (Oxycon mobile device) during whole cycling sessions
4. Time of cycling sessions, recorded by stopwatch
5. Perceived exertion, assessed twice at predefined parcours locations with Borg scale
Kcal, deduced from VO2 and total time of cycling sessions

VCO2, RER, VE, perceived exertion (Borg scale) were recorded during all cycling sessions.

VO2 or oxygen consumption - VO2 is defined as the volume of O2 extracted from inspired air in a given period of time.
VCO2 or carbon dioxide output - VCO2 is defined as the amount of CO2 exhaled from the body per unit of time.
RER or respiratory exchange ratio - RER is defined as : RER= VCO2/VO2. The RER is determined

by the fuels used for metabolism. RER is 1 for carbohydrates; RER is 0,7 for lipids and RER is 0,85 for carbohydrates and lipids.
VE or minute ventilation - VE is the volume of expired air exhaled from the lungs in 1 minute.

Overall study start date
01/11/2014

Completion date
01/05/2015

Eligibility

Key inclusion criteria
1. Coronary artery disease patients, treated with percutaneous coronary intervention or coronary artery bypass grafting
2. Patients should have completed phase II of cardiac rehabilitation
3. Absence of severe pulmonary and/or renal disease
4. Absence of neurological and/or orthopedic disease (that would limit the patient's possibility to cycle)
5. Absence of pacemaker
6. Gender: both male and female
7. Age: between 50-75 years old
8. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
15

Key exclusion criteria
1. Presence of severe pulmonary and/or renal disease
2. Presence of neurological and/or orthopedic disease (that would limit the patient's possibility to cycle)
3. Presence of pacemaker
4. Age: <50 or > 75 years old

Date of first enrolment
10/11/2014

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
Belgium

Study participating centre
Jessa Hospital
Stadsomvaart 11
3500 Hasselt
Hasselt
Belgium
3500

Sponsor information

Organisation
Heart Center Hasselt

Sponsor details
Stadsomvaart 11
3500 Hasselt
Hasselt
Belgium
3500

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03tw90478

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Heart Center Hasselt (Belgium)

Results and Publications

Publication and dissemination plan

Publication: submission of article by September 2015.
Dissemination: presentation of trial results at the Belgian Society of Cardiology (BSC) conference 2016.

Intention to publish date
01/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018	22/01/2019	Yes	No